

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

m2482n

Food and Drug Administration 555 Winderley Place, Suite 200 Maitland, Florida 32751

## CERTIFIED MAIL RETURN RECEIPT REQUESTED

Ref:

Customs Entry No. 336-2105512-0

Steak Sauce

## WARNING LETTER

FLA-99-42

March 1, 1999

Mr. Raja Shah President/Owner Elite International Corporation 911 Cold Spring Drive Northville, MI 48167

Dear Mr. Shah:

The Food and Drug Administration (FDA) attempted to examine a shipment of steak sauce offered for entry into the United States by your firm on January 13, 1999, under the above referenced entry, and found that the shipment was not available for examination. Regulation Title 21, Code of Federal Regulations (CFR), Part 1.90, requires to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We have requested the U. S. Customs Service (Customs) to order redelivery of this shipment (copy enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation. In addition, you should inform Customs and FDA if and when redelivery is accomplished.

Mr. Raja Shah Page 2 March 1, 1999

Your written reply should be addressed to the Food and Drug Administration, Attention: Kendall W. Hester, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4730.

Sincerely,

Douglas D. Tolen

Director, Florida District

Enclosure